DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
9 3063d
San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 2939890

January 25, 2002

L. Neal Jones, President/Owner
Toma Tek
16th and Simpson Streets
P.O. Box 30
Vancouver, WA 98666

WARNING LETTER

Dear Mr. Jones:

The U S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 2502 "N" Street, Firebaugh, CA on April 2 and 4, 2001. A review of the labels of your Old California brand tomato products reveals that the products are misbranded within the meaning of Section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) because their labeling is false or misleading.

Your Old California brand tomato products are misbranded because the phrase "FRESH FROM THE FIELD," as it appears on the label implies that the finished product is "fresh," when, in fact, it has been thermally processed. We would not object to the use of the term "fresh" in the context of a statement such as "packed from" or "made with" fresh from the field tomatoes, provided that the tomatoes were indeed fresh as defined in Title 21, Code of Federal Regulations, Part 101.95 (21 CFR 101.95) when they were added to the product.

The inspection also found that you have failed to provide the FDA information on the scheduled processes for your acidified product, Corner Bakery brand Marinara Sauce, as required by 21 CFR 108.25(c)(2). Accordingly, records are not maintained of the examination of raw materials and packaging materials for this product to verify compliance with FDA regulations and guidelines or action levels, as required by 21 CFR 114.100(a)

At the conclusion of the inspection, some of the above deviations were listed on Form FDA 483 (Inspectional Observations) and discussed with John Cranfield, Plant Manager. A copy of this form is enclosed for your ready reference. This list is not meant to be an

all-inclusive list of violations. As a manufacturer of food products, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in FDA compliance with all applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

Your reply should be directed to Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda 94502-7070. If you have any questions concerning the violations noted, then please contact Ms. Kishida at (510) 337-6824.

Sincerely,

Dennis K. Linsley
District Director
San Francisco District

Enclosure

cc John Cranfield, Plant Manager
Toma Tek
2502 "N" Street
Firebaugh, CA 93622